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Mr. C. Joseph Støtler President Pharmaceutical Manufacturers Association 1155 Fifteenth Street, N.W.

Dear Mr. Stetler:

Washington, D.C. 20005

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Thank you for your letter concerning this Department's patent policies. I agree that our review of petitions for waiver of principal invention rights should be completed in a timely manner. I am pleased to inform you that the backlog that had built up as a result of the tighter Departmental review procedures has been eliminated.

In addition to instituting better reviews of applications, I have also asked the General Counsel to review our general patent policy. This review is still in its preliminary stages, and no decisions have been reached.

The General Counsel's study of HEM's patent policies includes an evaluation of the objectives of those policies, as well as an evaluation of the options available. A draft paper, now being circulated within the Department, discusses several ideas which may or may not be adopted as policy. I understand that the language you quoted is from that draft.

I expect to receive the completed study soon. At that time, I will consider your comments as well as those of other interested parties, in deciding whether policy changes should be considered. Any substantial changes in current policies will most likely be implemented with the publication, after an appropriate comment period, of new regulations.

Any study conducted by GAO would be independent of this Department, and I suggest that you contact the General Accounting Office directly if you wish to communicate your views to them.

## Page 2 - Mr. C. Joseph Stetler

Let me assure you that the primary objective of any policy adopted by this Department will be to ensure that inventions developed with funding from public money are introduced in a way that will best serve the public interest. In most cases this would mean bringing the invention to the public as quickly and economically as possible.

Sincerely,

/s/ Hale Champion

Joseph A. Califano, Jr.

Retyped: MAndrew/ESP/11/7/78 cc: DHEW/OS/OGC